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| APPLICATION NO.  | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|----------------|----------------------|-------------------------|------------------|
| 10/076,418   | 02/19/2002     | Maria Dalko          | 010830-121              | 9294             |
| 7:   | 590 08/20/2002 |                      |                         |                  |
| Norman H. Stepno, Esquire<br>BURNS, DOANE, SWECKER & MATHIS, L.L.P.<br>P.O. Box 1404 |                |                      | EXAMINER                |                  |
|  |                |                      | MELLER, MICHAEL V       |                  |
| Alexandria, VA 22313-1404  |                |                      | ART UNIT                | PAPER NUMBER     |
|  |                |                      | 1651                    |                  |
|  |                |                      | DATE MAILED: 08/20/2002 | ζ                |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.  | Applicant(s)   |  |  |  |  |
|---|--|--|--|--|--|--|
| Office Action Summany   | 10/076,418   | DALKO ET AL.   |  |  |  |  |
| Office Action Summary   | Examiner   | Art Unit   |  |  |  |  |
|   | Michael V. Meller  | 1651   |  |  |  |  |
| The MAILING DATE of this c mmunication appears n the cover sheet with the corresp ndence address Period for Reply   |  |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status | 36(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |  |
| 1) Responsive to communication(s) filed on  | <u> </u>   |  |  |  |  |  |
| 2a) This action is <b>FINAL</b> . 2b) This  | is action is non-final.  |  |  |  |  |  |
| 3) Since this application is in condition for allowa  |  |  |  |  |  |  |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. <b>Disposition of Claims</b>  |  |  |  |  |  |  |
| 4) Claim(s) <u>1-30</u> is/are pending in the application   |  |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrav   | vn from consideration.   |  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |  |  |  |  |  |  |
| 6)☐ Claim(s) is/are rejected.   |  |  |  |  |  |  |
| 7) Claim(s) is/are objected to.   |  |  |  |  |  |  |
| 8) Claim(s) 1-30 are subject to restriction and/or election requirement.  |  |  |  |  |  |  |
| Application Papers  9)☐ The specification is objected to by the Examiner  |  |  |  |  |  |  |
|   |  | miner  |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |  |  |  |  |  |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.  |  |  |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |  |  |  |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.   |  |  |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |  |  |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |  |  |  |  |  |  |
| a) All b) Some * c) None of:  |  |  |  |  |  |  |
| 1. Certified copies of the priority documents   | s have been received.  |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |  |  |  |  |  |  |
| <ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |  |  |  |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |  |  |  |  |  |  |
| a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.   |  |  |  |  |  |  |
| Attachment(s)   |  |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)   | 5) Notice of Informal I  | v (PTO-413) Paper No(s)<br>Patent Application (PTO-152)  |  |  |  |  |

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## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, 11-17, drawn to a composition, classified in class 435, subclass 183.
- II. Claims 9 and 10, drawn to a composition (kit), classified in class 424, subclass various.
- III. Claims 18-24, drawn to a method of making said kit, classified in class514, subclass various.
- IV. Claim 25, drawn to a method of using said composition, classified in class530, subclass various.
- V. Claims 26-30, drawn to a method of using a second composition, classified in class 530, subclass various.

The inventions are distinct, each from the other because of the following reasons:

Inventions III and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2)

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that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a materially distinct process such as genetic engineering.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a materially distinct process such as treating wounds.

Inventions I and II are distinct from one another since the components are separated and when they are together they have different chemical properties, functions, etc.

The other inventions are unrelated to each other since they are not used together and involve different modes of operation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: the many different components in the composition.

Applicant is required to enumerate all of the specific components in the composition to be used.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 18, 25 and 26 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Michael V. Meller Examiner

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MVM

August 19, 2002